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EXAMINER

LACOURCIERE, KAREN A

ART UNIT PAPER NUMBER

1635

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15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/489,873

Applicant(s)

KARSENTY ET AL.

Examiner

Karen Lacourciere

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-60 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C.

121:

- I. Claims 1-5, 18 and 19, drawn to a method of treating a bone disease by administering a polynucleotide that lowers leptin levels, classified in class 514, subclass 44.
- II. Claims 1, 5-13 and 16-19, drawn to a method of treating a bone disease by administering an antibody that binds leptin, classified in class 514, subclass 2.
- III. Claims 1, 5-8, 12, 18 and 19, drawn to a method of treating a bone disease by administering a soluble leptin receptor, classified in class 514, subclass 2.
- IV. Claims 1, 5-8, 12, 18 and 19, drawn to a method of treating a bone disease by administering an inter-alpha-trypsin inhibitor heavy chain, classified in class 514, subclass 2.
- V. Claims 1, 5-8, 12, 18 and 19, drawn to a method of treating a bone disease by administering an alpha 2-macroglobulin protein, classified in class 514, subclass 2.
- VI. Claims 13-15 and 17-19 drawn to a method of treating a bone disease by administering an acetylphenol, classified in class 514, subclass 1.

- VII. Claims 13, 14, 16, 17, 18 and 19, drawn to a method of treating a bone disease by administering an antibody that binds leptin receptor, classified in class 514, subclass 2.
- VIII. Claims 20-24, drawn to a method of preventing a bone disease by administering a polynucleotide that lowers leptin levels, classified in class 514, subclass 44.
- IX. Claims 20, 24-32, 35 and 36, drawn to a method of preventing a bone disease by administering an antibody that binds leptin, classified in class 514, subclass 44.
- X. Claims 20, 24-27, 31, 32, 35 and 36, drawn to a method of preventing a bone disease by administering a soluble leptin receptor, classified in class 514, subclass 2.
- XI. Claims 20, 24-27, 31, 32, 35 and 36, drawn to a method of preventing a bone disease by administering an inter-alpha-trypsin inhibitor heavy chain, classified in class 514, subclass 2.
- XII. Claims 20, 24-27, 31, 32, 35 and 36, drawn to a method of preventing a bone disease by administering an alpha 2-macroglobulin protein, classified in class 514, subclass 2.
- XIII. Claims 32-34 and 36, drawn to a method of preventing a bone disease by administering an acetylphenol, classified in class 514, subclass 1.

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- XIV. Claims 37-39, drawn to a method of diagnosing a bone disease in a mammal by measuring the level of leptin in blood serum, classified in class 435, subclass 7.1.
- XV. Claims 40-42, drawn to a method of diagnosing a bone disease in a mammal by measuring the level of leptin in cerebrospinal fluid, classified in class 435, subclass 7.1.
- XVI. Claims 43-60, drawn to a method of identifying a compound that modulates bone mass in a mammal, classified in class 435, subclass 7.1.

Applicant should note some claims are generic to more than one group.

Upon election of one invention, these generic claims will only be examined to the extent that they read on the elected invention.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods which are not capable of use together and have different modes of operation. For example, the methods of Group I utilize a polynucleotide, which is composed of nucleic acids, and operates by inhibiting the expression of leptin. This is different than the methods of Group II, which

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utilize an antibody, which is composed of amino acids and operates by increasing the breakdown of leptin.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods which are not capable of use together and have different modes of operation. For example, the methods of Group I utilize a polynucleotide, which is composed of nucleic acids, and operates by inhibiting the expression of leptin. This is different than the methods of Group III, which utilize a leptin receptor, which is composed of amino acids and operates by binding to leptin and preventing its activity.

Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods which are not capable of use together and have different modes of operation. For example, the methods of Group I utilize a polynucleotide, which is composed of nucleic acids, and operates by inhibiting the expression of leptin. This is different than the methods of Group III, which utilize an inter-alpha-trypsin inhibitor heavy chain, which is composed of amino acids and operates by binding Ob and inhibiting Ob binding to the Ob receptor.

Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different are drawn to materially different methods which are not capable of use together and have different modes of operation. For example, the methods of Group I utilize a polynucleotide, which is composed of nucleic acids, and operates by inhibiting the expression of leptin. This is different than the methods of Group V, which utilize an alpha 2-macroglobulin protein, which is composed of amino acids and operates by binding to OB and inhibiting its binding to the Ob receptor.

Inventions I and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different are drawn to materially different methods which are not capable of use together and have different modes of operation. For example, the methods of Group I utilize a polynucleotide, which is composed of nucleic acids, and operates by inhibiting the expression of leptin. This is different than the methods of Group VI, which utilize acetylphenol, which is a small molecule inhibitor and operates by binding to the Ob receptor and inhibiting Ob binding.

Inventions I and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §

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806.04, MPEP § 808.01). In the instant case the different are drawn to materially different methods which are not capable of use together and have different modes of operation. For example, the methods of Group I utilize a polynucleotide, which is composed of nucleic acids, and operates by inhibiting the expression of leptin. This is different than the methods of Group VII, which utilize an antibody, which is composed of amino acids and operates by binding to a leptin receptor to increase leptin receptor breakdown.

Inventions I and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different are drawn to methods which are not capable of use together and have different effects. For example, the methods of Group I are drawn to methods of treating a bone disease, wherein the method is performed using a mammal which has a bone disease, and has the effect of ameliorating the bone disease, whereas the methods of Group VIII are drawn to preventing the occurrence of a bone disease and are performed using a mammal which does not have a bone disease and has the effect of preventing a bone disease from occurring in the mammal.

Inventions I and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different are drawn to materially different methods which are not capable of use together and have different

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modes of operation and different effects. For example, the methods of Group I utilize a polynucleotide, which is composed of nucleic acids, and are performed using a mammal which has a bone disease, and operates by inhibiting the expression of leptin and has the effect of treating a bone disease. This is different than the methods of Group IX, which utilize an antibody, which is composed of amino acids, and is performed using a mammal which does not have a bone disease, and operates by increasing the breakdown of leptin and has the effect of preventing a bone disease from occurring in the mammal.

Inventions I and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different are drawn to materially different methods which are not capable of use together and have different modes of operation and different effects. For example, the methods of Group I utilize a polynucleotide, which is composed of nucleic acids, and are performed using a mammal which has a bone disease, and operates by inhibiting the expression of leptin and has the effect of treating a bone disease. This is different than the methods of Group X, which utilize a leptin receptor, which is composed of amino acids, and is performed using a mammal which does not have a bone disease, and operates by binding to leptin and preventing its activity and has the effect of preventing a bone disease from occurring in the mammal.

Inventions I and XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have

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different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different are drawn to materially different methods which are not capable of use together and have different modes of operation and different effects. For example, the methods of Group I utilize a polynucleotide, which is composed of nucleic acids, and are performed using a mammal which has a bone disease, and operates by inhibiting the expression of leptin and has the effect of treating a bone disease. This is different than the methods of Group XII, which utilize an inter-alpha-trypsin inhibitor chain, which is composed of amino acids, and is performed using a mammal which does not have a bone disease, and operates by binding to Ob and inhibiting Ob binding to the Ob receptor and has the effect of preventing a bone disease from occurring in the mammal.

Inventions I and XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different are drawn to materially different methods which are not capable of use together and have different modes of operation and different effects. For example, the methods of Group I utilize a polynucleotide, which is composed of nucleic acids, and are performed using a mammal which has a bone disease, and operates by inhibiting the expression of leptin and has the effect of treating a bone disease. This is different than the methods of Group XII, which utilize an alpha 2-macroglobulin protein, which is composed of amino acids, and is performed using a mammal

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which does not have a bone disease, and operates by binding to Ob and inhibiting Ob binding to the Ob receptor and has the effect of preventing a bone disease from occurring in the mammal.

Inventions I and XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different are drawn to materially different methods which are not capable of use together and have different modes of operation and different effects. For example, the methods of Group I utilize a polynucleotide, which is composed of nucleic acids, and are performed using a mammal which has a bone disease, and operates by inhibiting the expression of leptin and has the effect of treating a bone disease. This is different than the methods of Group XIII, which utilize acetylphenol, which is a small molecule inhibitor, and is performed using a mammal which does not have a bone disease, and operates by binding to the Ob receptor and has the effect of preventing a bone disease from occurring in the mammal.

Inventions I and XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together, have different method steps and different effects. For example, the methods of Group I are drawn to methods of treating a bone disease in a mammal, and comprise steps of administering a

leptin inhibitor and have the effect of ameliorating a bone disease in the mammal, whereas the methods of Group XIV are drawn to methods of diagnosing a bone disease and comprise steps wherein the level of leptin is determined in blood serum and the methods have the effect of determining whether a mammal has a bone disease.

Inventions I and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together, have different method steps and different effects. For example, the methods of Group I are drawn to methods of treating a bone disease in a mammal, and comprise steps of administering a leptin inhibitor and have the effect of ameliorating a bone disease in the mammal, whereas the methods of Group XV are drawn to methods of diagnosing a bone disease and comprise steps wherein the level of leptin is determined in cerebrospinal fluid and the methods have the effect of determining whether a mammal has a bone disease.

Inventions I and XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together, have different method steps and different effects. For example, the methods of Group I are drawn to methods

of treating a bone disease in a mammal, and comprise steps of administering a leptin inhibitor and have the effect of ameliorating a bone disease in the mammal, whereas the methods of Group XVI are drawn to methods of identifying a compound that modulates bone mass and has the effect of identifying a compound with the ability to inhibit the activity of leptin.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together and have different modes of operation. For example, the methods of Group II operate by administering an antibody targeted to leptin, which acts by increasing the breakdown of leptin, such antibodies are structurally different than the leptin receptors administered in the methods of Group III, which operate by binding leptin and preventing leptin from binding the natural receptor and thereby preventing its activity.

Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together and have different modes of operation. For example, the methods of Group II operate by administering an antibody targeted to leptin, which acts by increasing the breakdown of leptin, such antibodies are structurally different than the inter-alpha-trypsin inhibitor

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heavy chain administered in the methods of Group IV, which operate by binding Ob and inhibiting its binding to the Ob receptor.

Inventions II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have *different modes of operation, different functions, or different effects* (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together and have different modes of operation. For example, the methods of Group II operate by administering an antibody targeted to leptin, which acts by increasing the breakdown of leptin, such antibodies are structurally different than the alpha 2-macroglobulin protein administered in the methods of Group V, which operate by binding to Ob and inhibiting Ob binding to the Ob receptor.

Inventions II and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have *different modes of operation, different functions, or different effects* (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods which are not capable of use together and have different modes of operation. For example, the methods of Group II operate by administering an antibody targeted to leptin, which is composed of amino acids and acts by inhibiting the activity of leptin, such antibodies are structurally different than the acetylphenol administered in the methods of Group VI, which is a small molecule inhibitor and which operates by binding to the Ob receptor and inhibiting Ob binding.

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Inventions II and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together and have different modes of operation. For example, the methods of Group II operate by administering an antibody targeted to leptin, which acts by increasing the breakdown of leptin, such antibodies are structurally different than the antibody targeted to a leptin receptor administered in the methods of Group VII, which operate by binding to a leptin receptor and increasing breakdown of the leptin receptor.

Inventions II and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different are drawn to materially different methods which are not capable of use together and have different modes of operation and different effects. For example, the methods of Group II, utilize an antibody, which is composed of amino acids, and is performed using a mammal which has a bone disease, and operates by increasing the breakdown of leptin and has the effect of treating a bone disease, whereas the methods of Group VIII utilize a polynucleotide, which is composed of nucleic acids, and are performed using a mammal which does not have a bone disease, and operates by inhibiting the expression of leptin and has the effect of preventing a bone disease from occurring in a mammal.

Inventions II and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different are drawn to methods which are not capable of use together and have different effects. For example, the methods of Group II, are performed using a mammal which has a bone disease and has the effect of treating a bone disease, whereas the methods of Group IX are performed using a mammal which does not have a bone disease, and has the effect of preventing a bone disease from occurring in a mammal.

Inventions II and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation and different effects. For example, the methods of Group II comprise administering an antibody which binds to leptin, operates by increasing breakdown of leptin, and is performed using a mammal which has a bone disease and has the effect of treating a bone disease. This is different than the methods of Group X, which comprise administering a leptin receptor, which is structurally different than the antibody of Group II, and operates by binding leptin and preventing it from binding the natural receptor and is performed using a mammal which does not have a bone disease and has the effect of preventing a bone disease from occurring in the mammal.

Inventions II and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation and different effects. For example, the methods of Group II comprise administering an antibody which binds to leptin, operates by increasing the breakdown of leptin, and is performed using a mammal which has a bone disease and has the effect of treating a bone disease. This is different than the methods of Group XI, which comprise administering an inter-alpha-trypsin inhibitor heavy chain, which is structurally different than the antibody of Group II, and operates by binding Ob an inhibiting binding of Ob to the Ob receptor and is performed using a mammal which does not have a bone disease and has the effect of preventing a bone disease from occurring in the mammal.

Inventions II and XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation and different effects. For example, the methods of Group II comprise administering an antibody which binds to leptin, operates by increasing the breakdown of leptin, and is performed using a mammal which has a bone disease and has the effect of treating a bone disease. This is different than the methods of Group XII, which

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comprise administering an alpha 2-macroglobulin protein, which is structurally different than the antibody of Group II, and operates by binding to Ob and inhibiting Ob binding to the Ob receptor and is performed using a mammal which does not have a bone disease and has the effect of preventing a bone disease from occurring in the mammal.

Inventions II and XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation and different effects. For example, the methods of Group II comprise administering an antibody which binds to leptin, operates by increasing leptin breakdown, and is performed using a mammal which has a bone disease and has the effect of treating a bone disease. This is different than the methods of Group XII, which comprise administering acetylphenol, which is structurally different than the antibody of Group II, and operates by binding to the Ob receptor and is performed using a mammal which does not have a bone disease and has the effect of preventing a bone disease from occurring in the mammal.

Inventions II and XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together, have different method steps

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and different effects. For example, the methods of Group II are drawn to methods of treating a bone disease in a mammal, and comprise steps of administering an antibody targeted to leptin and have the effect of ameliorating a bone disease in the mammal, whereas the methods of Group XIV are drawn to methods of diagnosing a bone disease and comprise steps wherein the level of leptin is determined in blood serum and the methods have the effect of determining whether a mammal has a bone disease.

Inventions II and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together, have different method steps and different effects. For example, the methods of Group II are drawn to methods of treating a bone disease in a mammal, and comprise steps of administering an antibody targeted to leptin and have the effect of ameliorating a bone disease in the mammal, whereas the methods of Group XV are drawn to methods of diagnosing a bone disease and comprise steps wherein the level of leptin is determined in cerebrospinal fluid and the methods have the effect of determining whether a mammal has a bone disease.

Inventions II and XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn

to methods which are not capable of use together, have different method steps and different effects. For example, the methods of Group II are drawn to methods of treating a bone disease in a mammal, and comprise steps of administering an antibody targeted to leptin and have the effect of ameliorating a bone disease in the mammal, whereas the methods of Group XVI are drawn to methods of identifying a compound that modulates bone mass and has the effect of identifying a compound with the ability to inhibit the activity of leptin.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together and have different modes of operation. For example, the methods of Group III operate by administering a leptin receptor, which acts by binding leptin and preventing its activity by preventing it from binding the natural receptor, these receptors are structurally different than inter-alpha-trypsin heavy chain administered in the methods of Group IV, which operate by binding to Ob and inhibiting Ob from binding to the Ob receptor.

Inventions III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together and have different modes of

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operation. For example, the methods of Group III operate by administering a leptin receptor, which acts by binding leptin and preventing its activity by preventing it from binding the natural receptor, these receptors are structurally different than the alpha 2-macroglobulin protein administered in the methods of Group V, which operate by binding to Ob and inhibiting Ob from binding to the Ob receptor.

Inventions III and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together and have different modes of operation. For example, the methods of Group III operate by administering a leptin receptor, which acts by binding leptin and preventing its activity by preventing it from binding the natural receptor, these receptors are structurally different than acetylphenol, a small molecule inhibitor, which is administered in the methods of Group IV, and which operates by binding to the Ob receptor.

Inventions III and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together and have different modes of operation. For example, the methods of Group III operate by administering a leptin receptor, which acts by binding leptin and preventing its activity by

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preventing it from binding the natural receptor, these receptors are structurally different than the antibody which binds to a leptin receptor administered in the methods of Group VI, which operate by increasing breakdown of the leptin receptor.

Inventions III and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together and have different modes of operation. For example, the methods of Group III operate by administering a leptin receptor, which is composed of amino acids and acts by binding leptin and preventing its activity by preventing it from binding the natural receptor and has the effect of treating a mammal with a bone disease, these receptors are structurally different than the polynucleotide administered in the methods of Group IV, which are composed of nucleic acids and operate by inhibiting the expression of leptin and have the effect of preventing a bone disease from occurring in a mammal which does not have a bone disease.

Inventions III and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation and different effects. For example, the methods of Group III comprise administering an leptin

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receptor, operates by binding to leptin preventing it from binding to the natural receptor, hereby inhibiting its activity, and is performed using a mammal which has a bone disease and has the effect of treating a bone disease. This is different than the methods of Group IX, which comprise administering an antibody that binds to leptin, which is structurally different than the receptors of Group III, and operates by increasing the breakdown of leptin and is performed using a mammal which does not have a bone disease and has the effect of preventing a bone disease from occurring in the mammal.

Inventions III and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods with different effects. For example, the methods of Group III are performed using a mammal which has a bone disease and has the effect of treating a bone disease. This is different than the methods of Group X, which are performed using a mammal which does not have a bone disease and has the effect of preventing a bone disease from occurring in the mammal.

Inventions III and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation and different effects. For example, the methods of Group III comprise administering an leptin

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receptor, operates by binding to leptin preventing it from binding to the natural receptor, hereby inhibiting its activity, and is performed using a mammal which has a bone disease and has the effect of treating a bone disease. This is different than the methods of Group XI, which comprise administering an inter-alpha-trypsin inhibitor heavy chain, which is structurally different than the receptors of Group III, and operates by binding to Ob and inhibiting Ob from binding to the Ob receptor and is performed using a mammal which does not have a bone disease and has the effect of preventing a bone disease from occurring in the mammal.

Inventions III and XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation and different effects. For example, the methods of Group III comprise administering an leptin receptor, operates by binding to leptin preventing it from binding to the natural receptor, hereby inhibiting its activity, and is performed using a mammal which has a bone disease and has the effect of treating a bone disease. This is different than the methods of Group XII, which comprise administering an alpha 2-macroglobulin protein, which is structurally different than the receptors of Group III, and operates by binding to Ob and inhibiting Ob from binding to the Ob receptor and is performed using a mammal which does not have a bone disease and has the effect of preventing a bone disease from occurring in the mammal.

Inventions III and XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation and different effects. For example, the methods of Group III comprise administering an leptin receptor, operate by binding to leptin preventing it from binding to the natural receptor, hereby inhibiting its activity, and is performed using a mammal which has a bone disease and has the effect of treating a bone disease. This is different than the methods of Group XIII, which comprise administering acetylphenol, which is structurally different than the receptors of Group III, and operates by binding to the Ob receptor and is performed using a mammal which does not have a bone disease and has the effect of preventing a bone disease from occurring in the mammal.

Inventions III and XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together, have different method steps and different effects. For example, the methods of Group III are drawn to methods of treating a bone disease in a mammal, and comprise steps of administering leptin receptor and have the effect of ameliorating a bone disease in the mammal, whereas the methods of Group XIV are drawn to methods of

diagnosing a bone disease and comprise steps wherein the level of leptin is determined in blood serum and the methods have the effect of determining whether a mammal has a bone disease.

Inventions III and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together, have different method steps and different effects. For example, the methods of Group III are drawn to methods of treating a bone disease in a mammal, and comprise steps of administering leptin receptor and have the effect of ameliorating a bone disease in the mammal, whereas the methods of Group XV are drawn to methods of diagnosing a bone disease and comprise steps wherein the level of leptin is determined in cerebrospinal fluid and the methods have the effect of determining whether a mammal has a bone disease.

Inventions III and XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together, have different method steps and different effects. For example, the methods of Group III are drawn to methods of treating a bone disease in a mammal, and comprise steps of administering a leptin receptor and have the effect of ameliorating a bone

disease in the mammal, whereas the methods of Group XVI are drawn to methods of identifying a compound that modulates bone mass and has the effect of identifying a compound with the ability to inhibit the activity of leptin.

Inventions IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation and different effects. For example, the methods of Group IV comprise administering an inter-alpha-trypsin heavy chain, operates by binding to Ob and inhibiting Ob from binding to the Ob receptor. This is different than the methods of Group V, which comprise administering an alpha 2-macroglobulin protein, which is structurally different than the inter-alpha-trypsin heavy chain of Group IV, and operates by binding to Ob and inhibiting Ob from binding to the Ob receptor.

Inventions IV and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation and different effects. For example, the methods of Group IV comprise administering an inter-alpha-trypsin heavy chain, operates by binding to Ob and inhibiting Ob from binding to the Ob receptor. This is different than the methods of Group VI, which comprise administering acetylphenol, which is structurally different than the inter-

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alpha-trypsin heavy chain of Group IV, and operates by binding to the Ob receptor.

Inventions IV and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation and different effects. For example, the methods of Group IV comprise administering an inter-alpha-trypsin heavy chain, operates by operates by binding to Ob and inhibiting Ob from binding to the Ob receptor. This is different than the methods of Group VII, which comprise administering an antibody that binds a leptin receptor, which is structurally different than the inter-alpha-trypsin heavy chain of Group IV, and operates by increasing breakdown of the leptin receptor, thereby inhibiting its activity.

Inventions IV and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together and have different modes of operation. For example, the methods of Group IV operate by administering a inter-alpha-trypsin heavy chain, which is composed of amino acids and acts by and has the effect of treating a mammal with a bone disease, these receptors are structurally different than the polynucleotide administered in the methods of

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Group VIII, which are composed of nucleic acids and operate by inhibiting the expression of leptin and have the effect of preventing a bone disease from occurring in a mammal which does not have a bone disease.

Inventions IV and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation and different effects. For example, the methods of Group IV comprise administering an inter-alpha-trypsin heavy chain, operates by operates by binding to Ob and inhibiting Ob from binding to the Ob receptor, thereby inhibiting its activity, and is performed using a mammal which has a bone disease and has the effect of treating a bone disease. This is different than the methods of Group IX, which comprise administering an antibody that binds to leptin, which is structurally different than the inter-alpha-trypsin heavy chain of Group IV, and operates by increasing the breakdown of leptin and is performed using a mammal which does not have a bone disease and has the effect of preventing a bone disease from occurring in the mammal.

Inventions IV and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation and different

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effects. For example, the methods of Group IV comprise administering an inter-alpha-trypsin heavy chain, operates by binding to Ob and inhibiting Ob from binding to the Ob receptor, thereby inhibiting its activity, and is performed using a mammal which has a bone disease and has the effect of treating a bone disease. This is different than the methods of Group X, which comprise administering a leptin receptor, which is structurally different than the inter-alpha-trypsin heavy chain of Group IV, and operates by binding leptin and preventing it from binding the natural receptor, and is performed using a mammal which does not have a bone disease and has the effect of preventing a bone disease from occurring in the mammal.

Inventions IV and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods with different effects. For example, the methods of Group IV are performed using a mammal which has a bone disease and has the effect of treating a bone disease. This is different than the methods of Group XI, which are performed using a mammal which does not have a bone disease and has the effect of preventing a bone disease from occurring in the mammal.

Inventions IV and XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn

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to materially different methods with different modes of operation and different effects. For example, the methods of Group IV comprise administering an inter-alpha-trypsin heavy chain, operates by operates by binding to Ob and inhibiting Ob from binding to the Ob receptor, thereby inhibiting its activity, and is performed using a mammal which has a bone disease and has the effect of treating a bone disease. This is different than the methods of Group XII, which comprise administering an alpha 2-macroglobulin protein, which is structurally different than the inter-alpha-trypsin heavy chain of Group IV, and operates by operates by binding to Ob and inhibiting Ob from binding to the Ob receptor and is performed using a mammal which does not have a bone disease and has the effect of preventing a bone disease from occurring in the mammal.

Inventions IV and XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation and different effects. For example, the methods of Group IV comprise administering an inter-alpha-trypsin heavy chain, operates by operates by binding to Ob and inhibiting Ob from binding to the Ob receptor, thereby inhibiting its activity, and is performed using a mammal which has a bone disease and has the effect of treating a bone disease. This is different than the methods of Group XIII, which comprise administering acetylphenol, which is structurally different than the inter-alpha-trypsin heavy chain of Group IV, and operates by binding to the Ob

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receptor and is performed using a mammal which does not have a bone disease and has the effect of preventing a bone disease from occurring in the mammal.

Inventions IV and XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together, have different method steps and different effects. For example, the methods of Group IV are drawn to methods of treating a bone disease in a mammal, and comprise steps of administering an inter-alpha-trypsin heavy chain and have the effect of ameliorating a bone disease in the mammal, whereas the methods of Group XIV are drawn to methods of diagnosing a bone disease and comprise steps wherein the level of leptin is determined in blood serum and the methods have the effect of determining whether a mammal has a bone disease.

Inventions IV and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together, have different method steps and different effects. For example, the methods of Group IV are drawn to methods of treating a bone disease in a mammal, and comprise steps of administering an inter-alpha-trypsin heavy chain and have the effect of ameliorating a bone disease in the mammal, whereas the methods of Group XV

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are drawn to methods of diagnosing a bone disease and comprise steps wherein the level of leptin is determined in cerebrospinal fluid and the methods have the effect of determining whether a mammal has a bone disease.

Inventions IV and XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together, have different method steps and different effects. For example, the methods of Group IV are drawn to methods of treating a bone disease in a mammal, and comprise steps of administering an inter-alpha-trypsin heavy chain and have the effect of ameliorating a bone disease in the mammal, whereas the methods of Group XVI are drawn to methods of identifying a compound that modulates bone mass and has the effect of identifying a compound with the ability to inhibit the activity of leptin.

Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation and different effects. For example, the methods of Group V comprise administering an alpha 2-macroglobulin protein, operates by binding to Ob and inhibiting Ob from binding to the Ob receptor. This is different than the methods of Group VI, which

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comprise administering acetylphenol, which is structurally different than the alpha 2-macroglobulin protein of Group V, and operates by binding to the Ob receptor.

Inventions V and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation and different effects. For example, the methods of Group V comprise administering an alpha 2-macroglobulin protein, operates by operates by binding to Ob and inhibiting Ob from binding to the Ob receptor. This is different than the methods of Group VII, which comprise administering an antibody that binds a leptin receptor, which is structurally different than the alpha 2-macroglobulin protein of Group V, and operates by increasing breakdown of the leptin receptor, thereby inhibiting its activity.

Inventions V and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together and have different modes of operation. For example, the methods of Group V operate by administering an alpha 2-macroglobulin protein, which is composed of amino acids and acts by and has the effect of treating a mammal with a bone disease, these receptors are structurally different than the polynucleotide administered in the methods of

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Group VIII, which are composed of nucleic acids and operate by inhibiting the expression of leptin and have the effect of preventing a bone disease from occurring in a mammal which does not have a bone disease.

Inventions V and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation and different effects. For example, the methods of Group V comprise administering an alpha 2-macroglobulin protein, operates by operates by binding to Ob and inhibiting Ob from binding to the Ob receptor, thereby inhibiting its activity, and is performed using a mammal which has a bone disease and has the effect of treating a bone disease. This is different than the methods of Group IX, which comprise administering an antibody that binds to leptin, which is structurally different than the alpha 2-macroglobulin protein of Group V, and operates by increasing the breakdown of leptin and is performed using a mammal which does not have a bone disease and has the effect of preventing a bone disease from occurring in the mammal.

Inventions V and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation and different

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effects. For example, the methods of Group V comprise administering an alpha 2-macroglobulin protein, operates by binding to Ob and inhibiting Ob from binding to the Ob receptor, thereby inhibiting its activity, and is performed using a mammal which has a bone disease and has the effect of treating a bone disease. This is different than the methods of Group X, which comprise administering a leptin receptor, which is structurally different than the alpha 2-macroglobulin protein of Group V, and operates by binding leptin and preventing it from binding the natural receptor, and is performed using a mammal which does not have a bone disease and has the effect of preventing a bone disease from occurring in the mammal.

Inventions V and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods with different effects. For example, the methods of Group V are performed using a mammal which has a bone disease and has the effect of treating a bone disease. This is different than the methods of Group XI, which are performed using a mammal which does not have a bone disease and has the effect of preventing a bone disease from occurring in the mammal.

Inventions V and XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn

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methods with different modes of operation and different effects. For example, the methods of Group V are performed using a mammal which has a bone disease and has the effect of treating a bone disease. This is different than the methods of Group XII, which are performed using a mammal which does not have a bone disease and has the effect of preventing a bone disease from occurring in the mammal.

Inventions V and XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation and different effects. For example, the methods of Group V comprise administering an alpha 2-macroglobulin protein, operate by binding to Ob and inhibiting Ob from binding to the Ob receptor, thereby inhibiting its activity, and is performed using a mammal which has a bone disease and has the effect of treating a bone disease. This is different than the methods of Group XIII, which comprise administering acetylphenol, which is structurally different than an alpha 2-macroglobulin protein of Group V, and operate by binding to the Ob receptor and is performed using a mammal which does not have a bone disease and has the effect of preventing a bone disease from occurring in the mammal.

Inventions V and XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §

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806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together, have different method steps and different effects. For example, the methods of Group V are drawn to methods of treating a bone disease in a mammal, and comprise steps of administering an alpha 2-macroglobulin protein and have the effect of ameliorating a bone disease in the mammal, whereas the methods of Group XIV are drawn to methods of diagnosing a bone disease and comprise steps wherein the level of leptin is determined in blood serum and the methods have the effect of determining whether a mammal has a bone disease.

Inventions V and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together, have different method steps and different effects. For example, the methods of Group V are drawn to methods of treating a bone disease in a mammal, and comprise steps of administering an alpha 2-macroglobulin protein and have the effect of ameliorating a bone disease in the mammal, whereas the methods of Group XV are drawn to methods of diagnosing a bone disease and comprise steps wherein the level of leptin is determined in cerebrospinal fluid and the methods have the effect of determining whether a mammal has a bone disease.

Inventions V and XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have

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different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together, have different method steps and different effects. For example, the methods of Group V are drawn to methods of treating a bone disease in a mammal, and comprise steps of administering an alpha 2-macroglobulin protein and have the effect of ameliorating a bone disease in the mammal, whereas the methods of Group XVI are drawn to methods of identifying a compound that modulates bone mass and has the effect of identifying a compound with the ability to inhibit the activity of leptin.

Inventions VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation and different effects. For example, the methods of Group VI comprise administering acetylphenol, a small molecule inhibitor and operate by binding to the Ob receptor. This is different than the methods of Group VII, which comprise administering an antibody that binds a leptin receptor, which is structurally different than acetylphenol of Group VI, and operate by increasing breakdown of the leptin receptor, thereby inhibiting its activity.

Inventions VI and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have

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different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together and have different modes of operation. For example, the methods of Group VI operate by administering acetylphenol, a small molecule inhibitor, and have the effect of treating a mammal with a bone disease, acetylphenol is structurally different than the polynucleotide administered in the methods of Group VIII, which are composed of nucleic acids and operate by inhibiting the expression of leptin and have the effect of preventing a bone disease from occurring in a mammal which does not have a bone disease.

Inventions VI and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation and different effects. For example, the methods of Group VI comprise administering acetylphenol, a small molecule inhibitor, and operate by binding to the Ob receptor, thereby inhibiting its activity, and are performed using a mammal which has a bone disease and has the effect of treating a bone disease. This is different than the methods of Group IX, which comprise administering an antibody that binds to leptin, which is structurally different than acetylphenol, and operate by increasing the breakdown of leptin and are performed using a

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mammal which does not have a bone disease and has the effect of preventing a bone disease from occurring in the mammal.

Inventions VI and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation and different effects. For example, the methods of Group VI comprise administering acetylphenol, a small molecule inhibitor, operate by binding to the Ob receptor and are performed using a mammal which has a bone disease and has the effect of treating a bone disease. This is different than the methods of Group X, which comprise administering a leptin receptor, which is structurally different than acetylphenol, and operate by binding leptin and preventing it from binding the natural receptor, and are performed using a mammal which does not have a bone disease and has the effect of preventing a bone disease from occurring in the mammal.

Inventions VI and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods with different effects. For example, the methods of Group VI comprise administering acetylphenol, a small molecule inhibitor, ^{are} ~~are~~ performed using a mammal which has a bone disease and has the effect of treating a bone

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disease. This is different than the methods of Group XI, which comprise administering an inter-alpha-trypsin inhibitor, which is structurally different than acetylphenol and operates by binding Ob, and are performed using a mammal which does not have a bone disease and have the effect of preventing a bone disease from occurring in the mammal.

Inventions VI and XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn methods with different modes of operation and different effects. For example, the methods of Group VI comprise administering acetylphenol, a small molecule inhibitor, and are performed using a mammal which has a bone disease and have the effect of treating a bone disease. This is different than the methods of Group XII, which comprise administering an alpha 2-macroglobulin protein, which is materially different than acetylphenol, and are performed using a mammal which does not have a bone disease and have the effect of preventing a bone disease from occurring in the mammal.

Inventions VI and XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation and different effects. For example, the methods of Group VI are performed using a mammal

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which has a bone disease and has the effect of treating a bone disease. This is different than the methods of Group XIII are performed using a mammal which does not have a bone disease and have the effect of preventing a bone disease from occurring in the mammal.

Inventions VI and XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together, have different method steps and different effects. For example, the methods of Group VI are drawn to methods of treating a bone disease in a mammal, and comprise steps of administering acetylphenol and have the effect of ameliorating a bone disease in the mammal, whereas the methods of Group XIV are drawn to methods of diagnosing a bone disease and comprise steps wherein the level of leptin is determined in blood serum and the methods have the effect of determining whether a mammal has a bone disease.

Inventions VI and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together, have different method steps and different effects. For example, the methods of Group VI are drawn to methods of treating a bone disease in a mammal, and comprise steps of

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administering acetylphenol and have the effect of ameliorating a bone disease in the mammal, whereas the methods of Group XV are drawn to methods of diagnosing a bone disease and comprise steps wherein the level of leptin is determined in cerebrospinal fluid and the methods have the effect of determining whether a mammal has a bone disease.

Inventions VI and XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together, have different method steps and different effects. For example, the methods of Group VI are drawn to methods of treating a bone disease in a mammal, and comprise steps of administering acetylphenol and have the effect of ameliorating a bone disease in the mammal, whereas the methods of Group XVI are drawn to methods of identifying a compound that modulates bone mass and has the effect of identifying a compound with the ability to inhibit the activity of leptin.

Inventions VII and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together and have different modes of operation. For example, the methods of Group VI operate by administering an antibody that binds to leptin, which is composed of amino acids, and operate by

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increasing the breakdown of leptin and have the effect of treating a mammal with a bone disease, these antibodies are structurally different than the polynucleotide administered in the methods of Group VIII, which are composed of nucleic acids and operate by inhibiting the expression of leptin and have the effect of preventing a bone disease from occurring in a mammal which does not have a bone disease.

Inventions VII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation and different effects. For example, the methods of Group VII comprise administering an antibody targeted to leptin and operate by increasing the breakdown of the leptin receptor, thereby inhibiting its activity, and are performed using a mammal which has a bone disease and has the effect of treating a bone disease. This is different than the methods of Group IX, which comprise administering an antibody that binds to leptin, which is structurally different than the antibody targeted to leptin receptor, and operate by increasing the breakdown of leptin and are performed using a mammal which does not have a bone disease and has the effect of preventing a bone disease from occurring in the mammal.

Inventions VII and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §

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806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation and different effects. For example, the methods of Group VII comprise administering an antibody that binds to leptin receptor, operate by increasing the breakdown of the leptin receptor and are performed using a mammal which has a bone disease and has the effect of treating a bone disease. This is different than the methods of Group X, which comprise administering a leptin receptor, and operate by binding leptin and preventing it from binding the natural receptor, and are performed using a mammal which does not have a bone disease and has the effect of preventing a bone disease from occurring in the mammal.

Inventions VII and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods with different effects. For example, the methods of Group VII comprise administering an antibody that binds to leptin receptor and operates by increasing the breakdown of leptin receptor and are performed using a mammal which has a bone disease and has the effect of treating a bone disease. This is different than the methods of Group XI, which comprise administering an inter-alpha-trypsin inhibitor, which is structurally different than the antibody targeted to leptin receptor, and operate by binding Ob, and are performed using a mammal which does not have a bone disease and have the effect of preventing a bone disease from occurring in the mammal.

Inventions VII and XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn methods with different modes of operation and different effects. For example, the methods of Group VII comprise administering an antibody that binds to leptin receptor and operates by increasing the breakdown of leptin receptor and are performed using a mammal which has a bone disease and have the effect of treating a bone disease. This is different than the methods of Group XII, which comprise administering an alpha 2-macroglobulin protein, and are performed using a mammal which does not have a bone disease and have the effect of preventing a bone disease from occurring in the mammal.

Inventions VII and XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation and different effects. For example, the methods of Group VII comprise administering an antibody targeted to leptin receptor and operate by increasing the breakdown of leptin receptor and are performed using a mammal which has a bone disease and have the effect of treating a bone disease. This is different than the methods of Group XIII, which comprise administering alpha 2-macroglobulin and operate by binding to Ob and are performed using a mammal which does not have a

bone disease and have the effect of preventing a bone disease from occurring in the mammal.

Inventions VII and XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together, have different method steps and different effects. For example, the methods of Group VII are drawn to methods of treating a bone disease in a mammal, and comprise steps of administering an antibody targeted to leptin receptor and operate by increasing the breakdown of leptin receptor and have the effect of ameliorating a bone disease in the mammal, whereas the methods of Group XIV are drawn to methods of diagnosing a bone disease and comprise steps wherein the level of leptin is determined in blood serum and the methods have the effect of determining whether a mammal has a bone disease.

Inventions VII and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together, have different method steps and different effects. For example, the methods of Group VII are drawn to methods of treating a bone disease in a mammal, and comprise steps of administering an antibody targeted to leptin receptor and have the effect of

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ameliorating a bone disease in the mammal, whereas the methods of Group XV are drawn to methods of diagnosing a bone disease and comprise steps wherein the level of leptin is determined in cerebrospinal fluid and the methods have the effect of determining whether a mammal has a bone disease.

Inventions VII and XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together, have different method steps and different effects. For example, the methods of Group VII are drawn to methods of treating a bone disease in a mammal, and comprise steps of administering an antibody targeted to leptin receptor and have the effect of ameliorating a bone disease in the mammal, whereas the methods of Group XVI are drawn to methods of identifying a compound that modulates bone mass and has the effect of identifying a compound with the ability to inhibit the activity of leptin.

Inventions VIII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different are drawn to materially different methods which are not capable of use together and have different modes of operation and different effects. For example, the methods of Group VIII utilize a polynucleotide, which is composed of nucleic acids, and operate by

inhibiting the expression of leptin. This is different than the methods of Group IX, which utilize an antibody, which is composed of amino acids and operate by increasing the breakdown of leptin.

Inventions VIII and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different are drawn to materially different methods which are not capable of use together and have different modes of operation. For example, the methods of Group VIII utilize a polynucleotide, which is composed of nucleic acids, and operate by inhibiting the expression of leptin. This is different than the methods of Group X, which utilize a leptin receptor, which is composed of amino acids and operate by binding to leptin and preventing its activity.

Inventions VIII and XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different are drawn to materially different methods which are not capable of use together and have different modes of operation. For example, the methods of Group VIII utilize a polynucleotide, which is composed of nucleic acids and operate by inhibiting the expression of leptin. This is different than the methods of Group XII, which utilize an inter-alpha-trypsin inhibitor chain, which is composed of amino acids, and operate by binding to Ob and inhibiting Ob binding to the Ob receptor.

Inventions VIII and XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different are drawn to materially different methods which are not capable of use together and have different modes of operation. For example, the methods of Group VIII utilize a polynucleotide, which is composed of nucleic acids and operate by inhibiting the expression of leptin. This is different than the methods of Group XII, which utilize an alpha 2-macroglobulin protein, which is composed of amino acids and operate by binding to Ob and inhibiting Ob binding to the Ob receptor.

Inventions VIII and XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different are drawn to materially different methods which are not capable of use together and have different modes of operation. For example, the methods of Group VIII utilize a polynucleotide, which is composed of nucleic acids and operate by inhibiting the expression of leptin. This is different than the methods of Group XIII, which utilize acetylphenol, which is a small molecule inhibitor and operate by binding to the Ob receptor.

Inventions VIII and XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §

806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together and have different method steps. For example, the methods of Group VIII are drawn to methods of preventing a bone disease in a mammal, and comprise steps of administering a leptin inhibitor and have the effect of preventing a bone disease in the mammal, whereas the methods of Group XIV are drawn to methods of diagnosing a bone disease and comprise steps wherein the level of leptin is determined in blood serum and the methods have the effect of determining whether a mammal has a bone disease.

Inventions VIII and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together, have different method steps and different effects. For example, the methods of Group VIII are drawn to methods of preventing a bone disease in a mammal, and comprise steps of administering a leptin inhibitor and have the effect of preventing a bone disease in the mammal, whereas the methods of Group XV are drawn to methods of diagnosing a bone disease and comprise steps wherein the level of leptin is determined in cerebrospinal fluid and the methods have the effect of determining whether a mammal has a bone disease.

Inventions VIII and XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have

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different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together, have different method steps and different effects. For example, the methods of Group VIII are drawn to methods of preventing a bone disease in a mammal, and comprise steps of administering a leptin inhibitor and have the effect of preventing a bone disease in the mammal, whereas the methods of Group XVI are drawn to methods of identifying a compound that modulates bone mass and has the effect of identifying a compound with the ability to inhibit the activity of leptin.

Inventions IX and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation. For example, the methods of Group IX comprise administering an antibody which binds to leptin and operates by increasing breakdown of leptin. This is different than the methods of Group X, which comprise administering a leptin receptor, which is structurally different than the antibody of Group IX, and operates by binding leptin and preventing it from binding the natural receptor.

Inventions IX and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn

to materially different methods with different modes of operation and different effects. For example, the methods of Group IX comprise administering an antibody which binds to leptin and operates by increasing the breakdown of leptin. This is different than the methods of Group XI, which comprise administering an inter-alpha-trypsin inhibitor heavy chain, which is structurally different than the antibody of Group IX, and operates by binding Ob and inhibiting binding of Ob to the Ob receptor.

Inventions IX and XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation. For example, the methods of Group IX comprise administering an antibody which binds to leptin and operates by increasing the breakdown of leptin. This is different than the methods of Group XII, which comprise administering an alpha 2-macroglobulin protein, which is structurally different than the antibody of Group II, and operates by binding to Ob and inhibiting Ob binding to the Ob receptor.

Inventions IX and XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation. For example, the methods of Group IX comprise administering an antibody which binds to

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leptin and operates by increasing leptin breakdown. This is different than the methods of Group XII, which comprise administering acetylphenol, which is structurally different than the antibody of Group IX and operates by binding to the Ob receptor.

Inventions IX and XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together, have different method steps and different effects. For example, the methods of Group IX are drawn to methods of preventing a bone disease in a mammal, and comprise steps of administering an antibody targeted to leptin and have the effect of preventing a bone disease in the mammal, whereas the methods of Group XIV are drawn to methods of diagnosing a bone disease and comprise steps wherein the level of leptin is determined in blood serum and the methods have the effect of determining whether a mammal has a bone disease.

Inventions IX and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together, have different method steps and different effects. For example, the methods of Group IX are drawn to methods of preventing a bone disease in a mammal, and comprise steps of

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administering an antibody targeted to leptin and have the effect of preventing a bone disease in the mammal, whereas the methods of Group XV are drawn to methods of diagnosing a bone disease and comprise steps wherein the level of leptin is determined in cerebrospinal fluid and the methods have the effect of determining whether a mammal has a bone disease.

Inventions IX and XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together, have different method steps and different effects. For example, the methods of Group IX are drawn to methods of preventing a bone disease in a mammal, and comprise steps of administering an antibody targeted to leptin and have the effect of preventing a bone disease in the mammal, whereas the methods of Group XVI are drawn to methods of identifying a compound that modulates bone mass and has the effect of identifying a compound with the ability to inhibit the activity of leptin.

Inventions X and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation. For example, the methods of Group X comprise administering an leptin receptor and operate by binding to leptin preventing it from binding to the natural receptor. This is

different than the methods of Group XI, which comprise administering an inter-alpha-trypsin inhibitor heavy chain, which is structurally different than the receptors of Group X and operates by binding to Ob and inhibiting Ob from binding to the Ob receptor.

Inventions X and XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation. For example, the methods of Group X comprise administering an leptin receptor and operate by binding to leptin preventing it from binding to the natural receptor. This is different than the methods of Group XII, which comprise administering an alpha 2-macroglobulin protein, which is structurally different than the receptors of Group X and operate by binding to Ob and inhibiting Ob from binding to the Ob receptor.

Inventions X and XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation. For example, the methods of Group X comprise administering an leptin receptor and operate by binding to leptin preventing it from binding to the natural receptor. This is different than the methods of Group XIII, which comprise administering

acetylphenol, which is structurally different than the receptors of Group X and operate by binding to the Ob receptor.

Inventions X and XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together, have different method steps and different effects. For example, the methods of Group X are drawn to methods of preventing a bone disease in a mammal, and comprise steps of administering leptin receptor and have the effect of preventing a bone disease in the mammal, whereas the methods of Group XIV are drawn to methods of diagnosing a bone disease and comprise steps wherein the level of leptin is determined in blood serum and the methods have the effect of determining whether a mammal has a bone disease.

Inventions X and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together, have different method steps and different effects. For example, the methods of Group X are drawn to methods of preventing a bone disease in a mammal, and comprise steps of administering leptin receptor and have the effect of preventing a bone disease in the mammal, whereas the methods of Group XV are drawn to methods of

diagnosing a bone disease and comprise steps wherein the level of leptin is determined in cerebrospinal fluid and the methods have the effect of determining whether a mammal has a bone disease.

Inventions X and XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together, have different method steps and different effects. For example, the methods of Group X are drawn to methods of preventing a bone disease in a mammal, and comprise steps of administering a leptin receptor and have the effect of preventing a bone disease in the mammal, whereas the methods of Group XVI are drawn to methods of identifying a compound that modulates bone mass and has the effect of identifying a compound with the ability to inhibit the activity of leptin.

Inventions XI and XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation. For example, the methods of Group XII comprise administering an inter-alpha-trypsin heavy chain and operate by binding to Ob and inhibiting Ob from binding to the Ob receptor. This is different than the methods of Group XII, which comprise administering an alpha 2-macroglobulin protein, which is structurally different

than the inter-alpha-trypsin heavy chain of Group IV, and operate by binding to Ob and inhibiting Ob from binding to the Ob receptor.

Inventions XI and XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation. For example, the methods of Group XI comprise administering an inter-alpha-trypsin heavy chain and operate by binding to Ob and inhibiting Ob from binding to the Ob receptor. This is different than the methods of Group XIII, which comprise administering acetylphenol, which is structurally different than the inter-alpha-trypsin heavy chain of Group XI, and operate by binding to the Ob receptor.

Inventions XI and XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together, have different method steps and different effects. For example, the methods of Group XI are drawn to methods of preventing a bone disease in a mammal, and comprise steps of administering an inter-alpha-trypsin heavy chain and have the effect of preventing a bone disease in the mammal, whereas the methods of Group XIV are drawn to methods of diagnosing a bone disease and comprise steps wherein

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the level of leptin is determined in blood serum and the methods have the effect of determining whether a mammal has a bone disease.

Inventions XI and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together, have different method steps and different effects. For example, the methods of Group XI are drawn to methods of treating a bone disease in a mammal, and comprise steps of administering an inter-alpha-trypsin heavy chain and have the effect of ameliorating a bone disease in the mammal, whereas the methods of Group XV are drawn to methods of diagnosing a bone disease and comprise steps wherein the level of leptin is determined in cerebrospinal fluid and the methods have the effect of determining whether a mammal has a bone disease.

Inventions XI and XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together, have different method steps and different effects. For example, the methods of Group XI are drawn to methods of preventing a bone disease in a mammal, and comprise steps of administering an inter-alpha-trypsin heavy chain and have the effect of preventing a bone disease in the mammal, whereas the methods of Group XVI

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are drawn to methods of identifying a compound that modulates bone mass and has the effect of identifying a compound with the ability to inhibit the activity of leptin.

Inventions XII and XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation. For example, the methods of Group XII comprise administering an alpha 2-macroglobulin protein and operate by binding to Ob and inhibiting Ob from binding to the Ob receptor. This is different than the methods of Group XIII, which comprise administering acetylphenol, which is structurally different than an alpha 2-macroglobulin protein of Group XII and operate by binding to the Ob receptor.

Inventions XII and XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together, have different method steps and different effects. For example, the methods of Group XII are drawn to methods of preventing a bone disease in a mammal, and comprise steps of administering an alpha 2-macroglobulin protein and have the effect of preventing a bone disease in the mammal, whereas the methods of Group XIV are drawn to methods of diagnosing a bone disease and comprise steps wherein the level of

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leptin is determined in blood serum and the methods have the effect of determining whether a mammal has a bone disease.

Inventions XII and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together, have different method steps and different effects. For example, the methods of Group XII are drawn to methods of preventing a bone disease in a mammal, and comprise steps of administering an alpha 2-macroglobulin protein and have the effect of preventing a bone disease in the mammal, whereas the methods of Group XV are drawn to methods of diagnosing a bone disease and comprise steps wherein the level of leptin is determined in cerebrospinal fluid and the methods have the effect of determining whether a mammal has a bone disease.

Inventions XII and XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together, have different method steps and different effects. For example, the methods of Group XII are drawn to methods of preventing a bone disease in a mammal, and comprise steps of administering an alpha 2-macroglobulin protein and have the effect of preventing a bone disease in the mammal, whereas the methods of Group XVI are drawn to

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methods of identifying a compound that modulates bone mass and has the effect of identifying a compound with the ability to inhibit the activity of leptin.

Inventions XIII and XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together, have different method steps and different effects. For example, the methods of Group XIII are drawn to methods of preventing a bone disease in a mammal, and comprise steps of administering acetylphenol and have the effect of preventing a bone disease in the mammal, whereas the methods of Group XIV are drawn to methods of diagnosing a bone disease and comprise steps wherein the level of leptin is determined in blood serum and the methods have the effect of determining whether a mammal has a bone disease.

Inventions XIII and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together, have different method steps and different effects. For example, the methods of Group XIII are drawn to methods of preventing a bone disease in a mammal, and comprise steps of administering acetylphenol and have the effect of preventing a bone disease in the mammal, whereas the methods of Group XV are drawn to methods of

diagnosing a bone disease and comprise steps wherein the level of leptin is determined in cerebrospinal fluid and the methods have the effect of determining whether a mammal has a bone disease.

Inventions XIII and XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together, have different method steps and different effects. For example, the methods of Group XIII are drawn to methods of preventing a bone disease in a mammal, and comprise steps of administering acetylphenol and have the effect of preventing a bone disease in the mammal, whereas the methods of Group XVI are drawn to methods of identifying a compound that modulates bone mass and has the effect of identifying a compound with the ability to inhibit the activity of leptin.

Inventions XIV and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not used together and have different modes of operation. For example, the methods of diagnosis of Group XIV operate by determining the level of leptin in blood serum and comprise steps wherein leptin is measured in blood serum, which is different than the methods of diagnosis of Group XV,

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which operate by determining levels of leptin in cerebral spinal fluid, and comprise steps wherein the level of leptin is measured in cerebral spinal fluid.

Inventions XV and XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not used together and have different effects. For example, the methods of Group XV have the effect of diagnosing a mammal for bone disease whereas the methods of Group XVI have the effect of identifying a compound that modulates bone mass in a mammal.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Lacourciere whose telephone number is (703) 308-7523. The examiner can normally be reached on Monday-Friday 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-1935 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Karen A. Lacourciere
September 3, 2002


PATENT EXAMINER